TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Burden Hours |
|---|---|---|---|---|---|
| 25.32(i) | 52 | 3 | 156 | 1 | 156 |
| 25.32(o) | 1 | 1 | 1 | 1 | 1 |
| 25.32(q) | 7 | 2 | 14 | 1 | 14 |
| Total | | | 171 | | 171 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The above estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, FDA has estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

Dated: March 22, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–5634 Filed 3–27–07; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. 2003E–0243 and 2003E–0244]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; INFUSE BONE GRAFT/LT–CAGE LUMBAR TAPERED FUSION DEVICE

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for INFUSE BONE GRAFT/LT–CAGE LUMBAR TAPERED FUSION DEVICE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of two applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that medical device.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device INFUSE BONE GRAFT/LT–CAGE LUMBAR TAPERED FUSION DEVICE. INFUSE BONE GRAFT/LT–CAGE LUMBAR TAPERED FUSION DEVICE is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L4—S1. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for INFUSE BONE GRAFT/LT–CAGE LUMBAR TAPERED FUSION DEVICE (U.S. Patent Nos. 5,782,919 and 5,984,967)) from SDGI Holdings, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated April 6, 2004, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of INFUSE BONE GRAFT/LT–CAGE LUMBAR TAPERED FUSION DEVICE represented the first permitted

commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for INFUSE BONE GRAFT/LT–CAGE LUMBAR TAPERED FUSION DEVICE is 2,052 days. Of this time, 1,515 days occurred during the testing phase of the regulatory review period, while 537 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: November 20, 1996. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective November 20, 1996.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: January 12, 2001. FDA has verified the applicant's claim that the premarket approval application (PMA) for INFUSE BONE GRAFT/LT–CAGE LUMBAR TAPERED FUSION DEVICE (PMA P000058) was initially submitted January 12, 2001.

3. *The date the application was approved*: July 2, 2002. FDA has verified the applicant's claim that PMA P000058 was approved on July 2, 2002.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 463 days of patent term extension for U.S. Patent No. 5,984,967 or 347 days of patent term extension for U.S. Patent No. 5,782,919.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 29, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 24, 2007. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 12, 2007.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. E7–5635 Filed 3–27–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Chicago District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA-regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

*Date and Time*: The public workshop is scheduled for May 16, 2007, from 8:30 a.m. to 5 p.m. and May 17, 2007, from 8:30 a.m. to 4:30 p.m.

*Location*: The public workshop will be held at the Oak Brook Hills Marriott Resort, 3500 Midwest Rd., Oak Brook, IL 60523, 630–850–5555, FAX: 630–850–5569.

*Contact*: Marie Falcone, Food and Drug Administration, U.S. Customhouse, 200 Chestnut St., rm. 900, Philadelphia, PA 19106, 215–717–3703, FAX: 215–597–5798, e-mail: *marie.falcone@fda.hhs.gov*.

*Registration*: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $575 (member), $650 (nonmember), or $525 (Federal Government employee nonmember). (Registration fee for nonmembers includes a 1-year membership.) The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, 530 West Butler Ave., suite 109, Chalfont, PA, 18914. To register via the Internet go to *www.socra.org* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–822–8644, or via e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Oak Brook Hills Marriott Resort, at the reduced conference rate, contact the Oak Brook Hills Marriott Resort (see *Location*) before April 24, 2007, citing meeting code SCRSCRA. The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials.

Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact Marie Falcone (see *Contact*) at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** The workshop on FDA clinical trials statutory and regulatory requirements helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. Topics for discussion include the following: (1) FDA regulation of the conduct of clinical research; (2) medical device, drug, biological and food product aspects of clinical research; (3) investigator initiated research; (4) pre-investigational new drug application meetings and FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of institutional review boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts bioresearch inspections; and (11) what happens after the FDA inspection. FDA